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This I sting of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. - 172. (Canceled)

173. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confi kince, loss of libic o, poor concentration, diminished energy, diminished drive, irritability, uragenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estre gen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverce effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Methal using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate.

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174. (Previously presented) A method of treating a disease, disorder or somptom associated with a deficient endogenous level of estrogen in a woman caused by inclural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palp:tations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of conf.c.;nce, loss of libi lo, poor concentration, diminished energy, diminished drive, irritability, u.c.genital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estragen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more it. in 10 000 cm²/g.

175. (Currently Amended) A method of treating a disease, disorder or sy aptom associated with a deficient endogenous level of estrogen in a woman caused by nateral menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palphictions, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of conficence, loss of libid, poor concentration, diminished energy, diminished drive, irritability, urcgenital

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atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distributio..., thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endog...ous level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adve. se effects of estrogen, wherein the drospirenone is micronized drospireneone has a particle size distribution such that not more than 2% of the particles have a diameter of more # an 30 µm.

- 176. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is: estradiol, an estradiol sulfamate, estradiol valerate, estradiol benzo ite, ethinyl estradiol, estrone, estriol, estriol succinate, a conjugated estrogen or a mixture thrusof.
- 177. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is: estradiol, an estradiol sulfamate, estradiol valerate, estradiol benzonte, estrone, estrone sulfate or a mixture thereof.
- 178. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is estradiol.
- 179. (Previously presented) A method according to claim 173, 174, or 175, wherein the estragen is in micronized form.

- 180. (Previously presented) A method according to claim 178, wherein the estradiol is in micronized form.
- 181. (Previously presented) A method according to claim 173, 174, or 175, wherein the dose of drospirenone corresponds to 15 to 70 mg per cycle.
- 182. (Previously presented) A method according to claim 173, 174, or 175, wherein the arrount of drospirenone corresponds to a daily dose ranging from 0.25 to 10 mg.
- 183. (Previously presented) A method according to claim 178, wherein the amount of estrudiol corresponds to a daily dose ranging from 0.1 to 5 mg.
- 184. (Previously presented) A method according to claim 178, wherein the amount of estradiol corresponds to a daily dose of about 0.1 to 5 mg.
- 185. (Previously presented) A method according to claim 178, comprising administering estradiol in a daily dose of 1 to 3 mg and drospirenone in a daily dose of 1 to 3.5 mg
- 186. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen and/or the drospirenone is administered in the form of a tablet, capsuse or pill.

- 187. (Previously presented) A method according to claim 173, 174, or 5, wherein the es rogen is: estrone sulfate, 17β-estradiol sulfate, 17α-estradiol sulfate, equilin sulfate, 17β-d hydroequilin sulfate, 17α-dihydroequilin sulfate, equilenin sulfate, 17β-dihydroequilenin sulfate, 17α-dihydroequilenin sulfate or a mixture thereof.
- 188. (Previously presented) A method according to claim 173, 174, or 175, wherein the daily dose of estrogen is 1 to 3 mg, and the daily dose of drospirenone is 0.25 to 10.0 mg.
- 189. (Previously presented) A method according to claim 173, 174, or 175, wherein the drespirenone is in the form of a prodrug of the compound.
- 190. (Currently Amended) A method according to claim 173, 174, or 175, wherein the drc spirenone is provided in a daily dose of 0.25 to 8.0 mg, in a form whereby it is exposed to the gastric environment upon dissolution.
- 191. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen is sprayed from a solution onto particles of an inert carrier.
- 192. (Currently Amended) A method according to claim 173, 174, or 175, wherein the espagen is micronized has a particle size distribution such that 100% of the particles have a diameter of \leq 15.0 μ m, 99% of the particles have a diameter of \leq 12.5 μ m, 95% of the particles have a diameter of \leq 10.0 μ m and 50% of the particles have a diameter of \leq 3.0 μ m.

193. - 194. (Canceled)

- 195. (Previously presented) A method according to claim 173, 174, or 1.75, wherein the estrogen and/or drospirenone are provided together with a carrier which productes rapid dissolution of the estrogen and/or drospirenone.
- 196. (Previously presented) A method according to claim 173, 174, or 175, wherein the es rogen and/or drospirenone is provided together with a carrier which comprises carbo: symethylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose gelled starch gelatin or polyvinylpyrrolidone.
- 197. (Previously presented) A method according to claim 173, 174, or 175, wherein the estrogen and/or drospirenone is provided together with a carrier which compilies polyvinylpyrrolidone.
- 198. (Previously presented) A method according to claim 178, wherein die dose of estradiol is about 1 mg.
- 199. (Previously presented) A method according to claim 178, wherein the dose of estradial is about 1 mg and the dose of drospirenone is about 0.5 mg, about 1 mg _bout 2 mg or about 3 mg.

- 200. (Previously presented) A method according to claim 173, 174, or 55, wherein the dose of drospirenone is from 0.25 to 6.0 mg.
- 201. (Previously presented) A method according to claim 173, 174, or : 5, wherein the dose of drospirenone is from 0.5 to 4.5 mg.
- 202. (Previously presented) A method according to claim 173, 174, or 175, wherein the dose of drospirenone is from 1.5 to 3.5 mg.
- 203. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menorause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, und genital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution thickness of hair changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endoger ous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenouse in 900

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ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP c issolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

a first treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 ing;

following the first treatment period, a second treatment period of 10 to 12 days comprising administering a daily dosage unit comprising estradiol in an amount corres conding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corres conding to a daily dose of about 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 cays comprising administering either: a daily dosage unit comprising estradiol in an aunumnt corresponding to a daily dose of about 0.25 to 5 mg or administering a daily dosage unit of a placebo or blank.

204. (Previously presented) A method of treating a disease, disorder or management associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confirtuce, loss of libic o, poor concentration, diminished energy, diminished drive, irritability, uragenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm²/g.

according to a treatment regimen including:

a first treatment period of 10 to 12 days comprising administering a daily disage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg;

following the first treatment period, a second treatment period of 10 to 12 days compr sing administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.25 to 5 mg or administering a daily dosage unit of a placebe or blank.

205. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by netural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting cil; hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety,

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poor remory, loss of confidence, loss of libido, poor concentration, diminished suergy, dimin shed drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition.

osteor orosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is micronized drospirenone has a particle gaze distribution such that not more than 2% of the particles have a diameter of more dan 30 μm, according to a treatment regimen including:

a first treatment period of 10 to 12 days comprising administering a daily dosage unit compr sing estradiol in an amount corresponding to a daily dose of about 0.1 to 5 ...19;

following the first treatment period, a second treatment period of 10 to 12 ways compr sing administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the second treatment period, a third treatment period of 4 to 8 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.25 to 5 mg or administering a daily dosage unit of a placebo or blank.

206. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural

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menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palphations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of configure, loss of libido, poor concentration, diminished energy, diminished drive, irritability, usegenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair changes in skin condition, osteoporosis or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverte effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of vater at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

a first treatment period of at least 21 days comprising administering a dail, losage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 x 5 mg and drospin; none in amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering: either a daily dosage unit of a placebo or blank or a daily dosage unit cor sprising estradiol in an amount corresponding to a daily dose of about 0.1 < 5 mg.

207. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by Leaural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, swearing attacks, palpi ations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, ure genital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogerous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symp.c.n, and drospirenone in a sufficient amount to protect the endometrium from adverte effects of estragen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm²/g,

according to a treatment regimen including:

a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospir none in amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering: either a daily dosage unit of a placebo or blank or a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 ± 5 mg.

208-(Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by untural menopause, peri-menopause, post-menopause, hypogonadism, castration or printary ovarian failur,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of configure, loss of libi to, poor concentration, diminished energy, diminished drive, irritability, use genital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estragen:

estradiol in a sufficient amount to alleviate said disease, disorder or sympam, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is micronized drospirencone has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 μm. according to a treatment regimen including:

a first treatment period of at least 21 days comprising administering a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 μ , 5 mg and drospirenone in amount corresponding to a daily dose of about 0.25 to 6 mg; and

following the first treatment period, a second treatment period of no more than 7 days comprising administering; either a daily dosage unit of a placebo or blank or a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 c. 5 mg.

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209. (Previously presented) A method of treating a disease, disorder or somptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primally ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palphations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of configurace, loss of libido, poor concentration, diminished energy, diminished drive, irritability, uregenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogen our level of estragen:

drospirenone in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverce effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% o 'said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen including:

administering for 21 to 28 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg.

210. (Previously presented) A method of treating a disease, disorder or staptom associated with a deficient endogenous level of estrogen in a woman caused by natural

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menopause, peri-menopause, post-menopause, hypogonadism, castration or prin:3,y ovarian failure,

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which disease, disorder or symptom is: hot flushes, sweating attacks, palpi-ations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of configence, loss of libi to, poor concentration, diminished energy, diminished drive, irritability, unigenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estragen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm²/g

according to a treatment regimen including:

administering for 21 to 28 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg.

211. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primaty ovarian failure

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss 17

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according to a treatment regimen including:

of libido, poor concentration, diminished energy, diminished drive, irritability, unigenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hai; changes in skin condition, osteoporosis, or a combination thereof;

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comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is micronized drospirencene has a particle rize distribution such that not more than 2% of the particles have a diameter of more than 30 µm,

administering for 21 to 28 days a daily dosage unit comprising estradiol in an amount corres conding to a daily dose of about 0.1 to 5 mg and drospirenone in an amour; corresponding to a daily dose of about 0.25 to 6 mg.

- (Previously presented) A method according to claim 209, 210 or 21, wherein 212. the da ly dosage units are administered for 1 to 12 cycles of 28 days per cycle.
- (Previously presented) A method of treating a disease, disorder or a mptom associated with a deficient endogenous level of estrogen in a woman caused by natural menoj ause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpications, sleep c isorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, unchenital 18

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atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of est ogen.

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from advaise effects of esti ogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenous in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP c issolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen wherein the estrogen is administered continuously.

A method of treating a disease, disorder or symptom 214. (Previously presented) associated with a deficient endogenous level of estrogen in a woman caused by retural menoj ause, peri-menopause, post-menopause, hypogonadism, castration or prima. y ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libi lo, poor concentration, diminished energy, diminished drive, irritability, ure genital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estragen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and 19

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drospirenone in a sufficient amount to protect the endometrium from adve. se effects of est ogen, wherein the drospirenone is in a form having a surface area of more tean 10 000 cm²/g.

according to a treatment regimen wherein the estrogen is administered corninuously.

215. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by taxtural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of configurace, loss of libi lo, poor concentration, diminished energy, diminished drive, irritability, u.v. genital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endoguanus level of estrogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is micronized drospireneone has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 µm, according to a treatment regimen wherein the estrogen is administered commonsty.

216. (Previously presented) A method according to claim 213, 214 or 215 wherein the drc spirenone is administered continuously.

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- (Previously presented) 217. A method according to claim 213, 214 or 215, wherein the drospirenone is administered in sequential intervals.
- (Previously presented) 218. A method according to claim 217, wherein Lie estrogen dosage is lower for the first 1 to 7 days immediately after finishing a sequential interval of admir istration of drospirenone.
- 219. (Previously presented) A method according to claim 218, wherein nie estrogen is adn inistered continuously for 21 to 30 days and drospirenone is administered in a 3-dayon-3-c ay-off cycle.
- 220. (Previously presented) A method according to claim 219, wherein drospi enone is administered on days 4 through 6, 10 through 12, 16 through 18, 22 through 24, and 28 through 30.
- (Previously presented) A method of treating a disease, disorder or symptom 221, associated with a deficient endogenous level of estrogen in a woman caused by natural menor ause, peri-menopause, post-menopause, hypogonadism, castration or primally ovarian failure,

which disease, disorder or symptom is selected from the group consisting with hot flushe:, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor n emory, loss of confidence, loss of libido, poor concentration, diminished crusrgy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular

disease, changes in hair distribution, thickness of hair, changes in skin condition. osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of est ogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or syn,ptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP cissolution test apparatus 2 and 50 rpm as the stirring rate,

according to a treatment regimen wherein the estrogen and the drospirenciae are each administered such that there is a treatment-free interval of 1-7 days within each cy :le.

(Previously presented) A method of treating a disease, disorder or symptom 222. associated with a deficient endogenous level of estrogen in a woman caused by madural menor ause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting call hot flushe:, sweating attacks, palpitations, sleep disorders, mood changes, nervousnes:, anxiety, poor n emory, loss of confidence, loss of libido, poor concentration, diminished creargy, dimini shed drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteop rosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogeitous level of est ogen:

an estrogen in a sufficient amount to alleviate said disease, disorder or syneptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm²/g

according to a treatment regimen wherein the estrogen and the drospirence, are each administered such that there is a treatment-free interval of 1-7 days within each wale.

223. (Currently Amended) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by tetural menorause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovaccular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteop prosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estragen:

an estrogen in a sufficient amount to alleviate said disease, disorder or symptom, and

drospirenone in a sufficient amount to protect the endometrium from adve.se effects of estrogen, wherein the drospirenone is micronized drospireneone has a particle: ize distribution such that not more than 2% of the particles have a diameter of more p an 30 µm,

according to a treatment regimen wherein the estroyen and the drospirenciae are each administered such that there is a treatment-free interval of 1-7 days within each cycle.

224. (Previously presented) A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by resural menor ause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushes, sweating attacks, palpitations, sleep disorders, mood changes, nervousnes, anxiety, poor nemory, loss of confidence, loss of libido, poor concentration, diminished or ergy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiovascular disease, changes in hair distribution, thickness of hair, changes in skin condition, osteop prosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogerous level of estrogen:

drospirenone in a sufficient amount to alleviate said disease, disorder or symptom, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% of said drospirenone is dissolved from a tablet containing 3 mg of drospirenone in 900 ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 and 50 rpm as the stirring rate.

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according to a treatment regimen including:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 .ng, and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg for the last 10 to 12 days of said 20 to 24 days, and

following the first treatment period, either: administering for 4 to 8 days a daily dosage unit comprising no active ingradient, administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less than daily dosage unit taken for said 20 to 24 day administration of estradio,, or not administering any dosage units for 4 to 8 days.

(Previously presented) 225. A method of treating a disease, disorder or symptom associated with a deficient endogenous level of estrogen in a woman caused by natural menopause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushe:, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished energy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiova a alar diseas:, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

comprising orally administering to a woman having such deficient endogenous level of estragen:

estradiol in a sufficient amount to alleviate said disease, disorder or sympsom, and

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drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm²/g

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according to a treatment regimen including:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 mg, and drospirenone in an amount corresponding to a daily dose of about 0.25 to 6 mg for the last 10 to 12 clays of said 20 to 24 days, and

following the first treatment period, either:

administering for 4 to 8 days a daily dosage unit comprising no active intridient. administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less than daily dosage unit taken for said 20 to 24 day administration of estradiot, or not administering any dosage units for 4 to 8 days.

A method of treating a disease, disorder or symptom **226.** (Currently Amended) associated with a deficient endogenous level of estrogen in a woman caused by natural menor ause, peri-menopause, post-menopause, hypogonadism, castration or primary ovarian failure,

which disease, disorder or symptom is selected from the group consisting of: hot flushe:, sweating attacks, palpitations, sleep disorders, mood changes, nervousness, anxiety, poor memory, loss of confidence, loss of libido, poor concentration, diminished carergy, diminished drive, irritability, urogenital atrophy, atrophy of the breasts, cardiova a alar disease, changes in hair distribution, thickness of hair, changes in skin condition, osteoporosis, or a combination thereof;

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comprising orally administering to a woman having such deficient endogenous level of estrogen:

estradiol in a sufficient amount to alleviate said disease, disorder or sympt .m, and drospirenone in a sufficient amount to protect the endometrium from advarse effects of esu ogen, wherein the drospirenone is micronized drospirencone has a particle 212e distribution such that not more than 2% of the particles have a diameter of more than 30 µm, according to a treatment regimen including:

a first treatment period of administering for 20 to 24 days a daily dosage unit comprising estradiol in an amount corresponding to a daily dose of about 0.1 to 5 ang, and drospi enone in an amount corresponding to a daily dose of about 0.25 to 6 mg for the last 10 to 12 cays of said 20 to 24 days, and

following the first treatment period, either:

administering for 4 to 8 days a daily dosage unit comprising no active ingadient, administering for 4 to 8 days a daily dosage of unit comprising estradiol in an amount less th in daily dosage unit taken for said 20 to 24 day administration of estradiol ... not administering any dosage units for 4 to 8 days.

A method for hormone replacement therapy comprising (Previously presented) orally idministering to a woman;

an estrogen in an amount sufficient for hormone replacement therapy, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrugen, wherein the drospirenone is in a form having a rapid dissolution such that at least 70% o 'said drospirenone is dissolved from a tablet containing 3 mg of drospirenos,e in 900

ml of water at 37°C within 30 minutes, as determined by USP XXIII Paddle Me.f.od using a USP c issolution test apparatus 2 and 50 rpm as the stirring rate.

228. (Previously presented) A method for hormone replacement therapy comprising orally administering to a woman;

an estrogen in an amount sufficient for hormone replacement therapy, and drospirenone in a sufficient amount to protect the endometrium from adverse effects of estrogen, wherein the drospirenone is in a form having a surface area of more than 10 000 cm²/g

229. (Currently Amended) A method for hormone replacement therapy comprising orally administering to a woman;

an estrogen in an amount sufficient for hormone replacement therapy, and drospirenone in a sufficient amount to protect the endometrium from advance effects of estrogen, wherein the drospirenone is micronized drospirenone has a particle size distribution such that not more than 2% of the particles have a diameter of more than 30 µm.

- 230. (Previously presented)

 A method according to claim 173 or 174, wherein the drospirenone is sprayed from a solution onto particles of an inert carrier.
- 231. (Canceled)
- 232. (Canceled)

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234. (New) A method according to one of claims 203 to 211, 213 to 2 15 or 221 to 229, wherein the drospirenone is provided in a form whereby it is exposed to the 4 astric environment upon dissolution.

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